REMARKS

Claim Status

Claims 1, 3-36 and 71 are pending in the present application. Claims 1, 3, 25, 31, 37, 49, and 71 have been amended. Support for the amendments are in the claims as filed and page 16, lines 32-34, and page 17, Lines 1-11.

The remaining claims, including the Examiner-renumbered Claims 72-78, have been withdrawn from consideration in response to a previous Restriction/Election requirement. No additional claims fee is believed to be due.

Rejection Under 35 USC §112, Second Paragraph

Claims 1-10, 13-14, 16, 19-20, 22 and 25 are rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

The Examiner asserts that the phrase "from about" and "at least about" are not defined by the claim and therefore indefinite. The Applicants respectfully traverse the rejections.

35 USC § 112 does not require Applicants to redefine in the claim each term when it is sufficiently defined in the specification as in the present case.

It is respectfully submitted that the term "about" as used in the present claims does not render the claims indefinite under 35 USC §112, Second Paragraph. As stated in the MPEP under 2173.05(b) A, the term "about" has been held to be "clear, but flexible" citing *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968) and *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). In *Gore*, the Court held that the use of "about" in defining stretching of a plastic at a rate "exceeding about 10% per second" is definite, since infringement could be assessed through the use of a stopwatch or timing device. By the same token, infringement of the present claimed method could be assessed by the use of a timing device if the duration of the treatment period were the issue.

In *Eastwood*, the Board of Appeals held that the term "about" used to define an area is definite stating as follows:

The descriptive word "about" is not indefinite as argued by the examiner. Its meaning is not as broad and arbitrary as contended by the examiner. Rather, the term is clear but flexible and is deemed to be similar in meaning to terms such as "approximately" or "nearly".

Even in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200; 18 USPQ.2D 1016 (Fed. Cir. 1991), which held that claims reciting "at least about 160,000" in defining specific activity of an erythropoietin protein were indefinite, the Court cautioned that such decision was reached because of the particular facts of the case, wherein the term could possibly include a value disclosed in the art. As stated therein:

In arriving at this conclusion, we caution that our holding that the term "about" renders indefinite claims 4 and 6 should not be understood as ruling out any and all uses of this term in patent claims. It may be acceptable in appropriate fact situations, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 U.S.P.Q. (BNA) 303, 316 (Fed. Cir. 1983) ("use of 'stretching . . . at a rate exceeding about 10% per second' in the claims is not indefinite"), even though it is not here.

It is respectfully submitted that the term "about" is recognized in US law to provide some expansion of the literal scope of the claims beyond the numeric range stated and that present Claims and present specification provides context and definition of the term "about" and the phrase "at least about". Various example ranges for ratio of stiffening agent to lipase inhibitor, and ranges for the amounts of stiffening agent and lipase inhibitor are provided in the specification. Therefore, one of skill in the art would understand the scope of the invention. Based on this, the Claims are fully definite as required by 35 USC §112, Second Paragraph. Therefore, the rejection of Claims 1-10, 13-14, 16, 19-20, 22 and 25 should be withdrawn.

Rejection Under 35 USC §103(a) Over de Smidt in view of Maeder

Claims 1-12, Claims 13 -24, and Claims 25-30 are rejected under 35 USC §103(a) as being unpatentable over US Patent 6,703,369 to de Smidt et al. ("de Smidt") in view of US Patent No. 6,730,319 to Maeder et al. ("Maeder").

The Applicants respectfully traverse the rejections. The Examiner has not met the burden of establishing a *prima facie* case of obviousness. See MPEP § 2143.01. In

order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

1. Claims 1-12

The Examiner states that de Smidt et al, teaches a pharmaceutical composition comprising a glyceride ester, with a melting point of 37°C and a lipase inhibitor. Neither de Smidt et al. nor Maeder et al. teaches or suggests the stiffening agents as recited in Claim 1. de Smidt discloses only compositions including lipase inhibitors in combination with fatty acid esters of polyols as a second component. See Column 2, lines 43-50. The current application claims and discloses mono-functional alcohols and not polyols. De smidt does not even mention or consider anything other than polyols. Maeder teaches only fatty acids and fatty acid salts, particularly sodium and potassium salts thereof, as a second component in addition to a lipase inhibitor. See Column 3, starting at line 12. Additionally, Maeder does not teach a ration of stiffening agent to lipase inhibitor, by weight, from at least 5:1.

The present invention is directed to composition useful for stiffening unabsorbed dietary fat and through such stiffening the viscosity of the substance in vivo resulting in the formation of solids, semisolids, pastes, and gels, See present specification page 8, lines 3-6. The Examiner states that Maeder et al. discloses a pharmaceutically active compound with a melting point > and or = to 37°C and fatty acid droplets below body temperature <37°C, See Column 3, line 25. Maeder et al. discloses that the invention provides pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form, See Column 3, lines 42-46. Applicants respectfully submit that it is error to find an invention obvious where prior art references diverges from the invention at hand. *W.L. Gore & Assocs. v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983). In determining obviousness, "[t]he claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and the obviousness of making the combination."

Lindeman Maschinenfabrick GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 1462 (Fed. Cir. 1984); *Maize*, 5 USPQ 1788, 1793 (Fed. Cir. 1988). "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02. The Maeder et al. reference discloses the pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form, See Column 3, lines 42-46. One of ordinary skill in the art would have no motivation to select the use of a pharmaceutical composition that provides exactly the opposite effect i.e. solid to liquid that the current invention sought to reverse i.e. liquid to non-liquid with the present invention . Applicants respectfully submit that if proposed modification would render the prior invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01 citing *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Furthermore, the Examiner asserts that a skilled artisan would be motivated to determine "the optimum amounts to get the maximum effect" but does not refer to amounts of what, what effect, or what "maximum" would be. The effect desired by de Smidt is to enhance the effectiveness of the lipase inhibitor. The effect desired by Maeder is to allow the lipase inhibitor to melt at a lower temperature and be distributed as a liquid in the body. Thus, there would potentially be different optimization criteria for the different desired effects, and therefore, one would not arrive at the present invention by mere optimization of the teachings and disclosure of either de Smidt or Maeder, taken either alone or in combination.

Even assuming *arguendo* that one were to combine de Smidt et al. and Maeder et al. one would still fall short of the Applicants' claimed invention. Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

2. Claims 13-24

The Examiner states that de Smidt et al, teaches a pharmaceutical composition comprising a glyceride ester, with a melting point of 37°C and a lipase inhibitor. Neither de Smidt et al. nor Maeder et al. teaches or suggests the stiffening agents as recited in Claim 1. de Smidt discloses only compositions including lipase inhibitors in combination with fatty acid esters of polyols as a second component. See Column 2, lines 43-50.

Maeder teaches only fatty acids and fatty acid salts, particularly sodium and potassium salts thereof, as a second component in addition to a lipase inhibitor. See Column 3, starting at line 12.

The present invention is directed to composition useful for stiffening unabsorbed dietary fat and through such stiffening the viscosity of the substance in vivo resulting in the formation of solids, semisolids, pastes, and gels, See present specification page 8, lines 3-6. The Examiner states that Maeder et al. discloses a pharmaceutically active compound with a melting point > and or = to 37°C and a fatty acids droplets below body temperature <37°C, See Column 3, line 25. Maeder et al. discloses that the invention provides pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form, See Column 3, lines 42-46. Applicants respectfully submit that it is error to find an invention obvious where prior art references diverges from the invention at hand. *W.L. Gore & Assocs. v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983). In determining obviousness, "[t]he claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a whole to suggest the desirability, and the obviousness of making the combination." *Lindeman Maschinenfabrick GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984); *Maize*, 5 USPQ 1788, 1793 (Fed. Cir. 1988). "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02. The Maeder et al. reference discloses the pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form, See Column 3, lines 42-46. One of ordinary skill in the art would have no motivation to select the use of a pharmaceutical composition that provides exactly the opposite effect i.e. solid to liquid that the current invention sought to reverse i.e. liquid to non-liquid with the present invention . Applicants respectfully submit that if proposed modification would render the prior invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01 citing *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Furthermore, the Examiner asserts that a skilled artisan would be motivated to determine "the optimum amounts to get the maximum effect" but does not refer to amounts of what, what effect, or what "maximum" would be. The effect desired by de

Smidt is to enhance the effectiveness of the lipase inhibitor. The effect desired by Maeder is to allow the lipase inhibitor to melt at a lower temperature and be distributed as a liquid in the body. Thus, there would potentially be different optimization criteria for the different desired effects, and therefore, one would not arrive at the present invention by mere optimization of the teachings and disclosure of either de Smidt or Maeder, taken either alone or in combination.

Even assuming *arguendo* that one were to combine de Smidt et al. and Maeder et al. one would still fall short of the Applicants' claimed invention. Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

3. Claims 25-30

The Examiner states that de Smidt et al, teaches a pharmaceutical composition comprising a glyceride ester, with a melting point of 37°C and a lipase inhibitor. Neither de Smidt et al. nor Maeder et al. teaches or suggests the stiffening agents as recited in Claim 1. de Smidt discloses only compositions including lipase inhibitors in combination with fatty acid esters of polyols as a second component. See Column 2, lines 43-50. Maeder teaches only fatty acids and fatty acid salts, particularly sodium and potassium salts thereof, as a second component in addition to a lipase inhibitor. See Column 3, starting at line 12.

The present invention is directed to composition useful for stiffening unabsorbed dietary fat and through such stiffening the viscosity of the substance in vivo resulting in the formation of solids, semisolids, pastes, and gels, See present specification page 8, lines 3-6.

The Examiner states that Maeder et al. discloses a pharmaceutically active compound with a melting point > and or = to 37°C and a fatty acids droplets below body temperature <37°C, See Column 3, line 25. Maeder et al. discloses that the invention provides pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form, See Column 3, lines 42-46. Applicants respectfully submit that it is error to find an invention obvious where prior art references diverges from the invention at hand. *W.L. Gore & Assocs. v. Garlock, Inc.*, 220 USPQ 303, 311 (Fed. Cir. 1983). In determining obviousness, "[t]he claimed invention must be considered as a whole, and the question is whether there is something in the prior art as a

whole to suggest the desirability, and the obviousness of making the combination." *Lindeman Maschinenfabrick GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462 (Fed. Cir. 1984); *Maize*, 5 USPQ 1788, 1793 (Fed. Cir. 1988). "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02. The Maeder et al. reference discloses the pharmaceutical compositions that are able to transform the active ingredient after oral ingestion from a solid to a liquid form, See Column 3, lines 42-46. One of ordinary skill in the art would have no motivation to select the use of a pharmaceutical composition that provides exactly the opposite effect i.e. solid to liquid that the current invention sought to reverse i.e. liquid to non-liquid with the present invention . Applicants respectfully submit that if proposed modification would render the prior invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. MPEP § 2143.01 citing *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Furthermore, the Examiner asserts that a skilled artisan would be motivated to determine "the optimum amounts to get the maximum effect" but does not refer to amounts of what, what effect, or what "maximum" would be. The effect desired by de Smidt is to enhance the effectiveness of the lipase inhibitor. The effect desired by Maeder is to allow the lipase inhibitor to melt at a lower temperature and be distributed as a liquid in the body. Thus, there would potentially be different optimization criteria for the different desired effects, and therefore, one would not arrive at the present invention by mere optimization of the teachings and disclosure of either de Smidt or Maeder, taken either alone or in combination.

Even assuming *arguendo* that one were to combine de Smidt et al. and Maeder et al. one would still fall short of the Applicants' claimed invention. Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

4. Claims 31-36 and 71

Claims 31-36 and 71 are stated as rejected under 35 USC §103(a) as being unpatentable over de Smidt in view of Maeder and US Patent 6,358,522 to Hug et al. with Hird et al. WO 02/074343.

With respect to Hird et al., Applicants respectfully traverse this rejection because the Hird et al. reference is not available as prior art against the present application under 35 U.S.C. §103(c).

The present application and the Hird et al. were, at the time the claimed invention was made, owned by, or subject to an obligation of assignment to, the Procter & Gamble Company.

35 U.S.C. §103(c) applies to U.S. patent applications filed after November 29, 1999. Since the current application has a filing date after November 29, 1999 (filed on October 31, 2003), Applicants contend that Hird et al. is not available as a reference under 35 U.S.C. §103(c).

However, if one were to consider Hird et al., Hird does not teach or suggest the stiffening agent of the current invention.

With respect to Claims 31-36, there is no teaching or suggestion in de Smidt, Maeder, or Hug or Hird et al. to use any sort of stiffening agent, alone, to stiffen lipophilic substances in the gastrointestinal tract. De Smidt, Maeder, and Hug or Hird et al. all require a combination of lipase inhibitor and additional components to enhance the function of the lipase inhibitor or to lower the melting point of the lipase inhibitor. Therefore, because there is no teaching or suggestion in any of the cited documents to use a stiffening agent alone, for stiffening lipophilic substances in the gastrointestinal tract, there can be no expectation of success for using such a stiffening agent alone in such a composition. Thus, the cited documents do not disclose all of the claim limitations. "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be **important** to identify **a reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way claimed new invention does. This is so because **inventions in most, if not all, instances rely upon building blocks since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.**" KSR, 1727 S. Ct. 1727, at 1741 (2007) (emphasis added). A quote acknowledging a "helpful insight" by the Court of Customs and Patent Appeals when that court first established TSM. "Often, it will be necessary for a court to

look to interrelated teachings of multiple patents; . . . **to determine whether there was an apparent reason** to combine the known elements in the fashion claimed by the patent at issue." KSR, 1727 S. Ct. at 1740-41 (emphasis added).

Particularly with respect to Hug and Claim 71, the Examiner states that Hug teaches one (or more) additive(s) of the group consisting of substantially non-digestable food grade thickeners and emulsifiers, and excipients. Hug teaches only the combination of a lipase inhibitor and one or more substantially non-digestable, substantially non-fermentable hydrophilic and/or hydrocolloidal food grade additives such as conventional thickeners and emulsifiers. Nowhere does Hug teach, suggest or define any type of foam compound as considered to be a conventional food grade thickener or emulsifier. See Hug, for example at column 2, line 25 through column 3, line 43.

Therefore, there is no teaching or suggestion in de Smidt, Maeder, or Hug or Hird et al. to use any sort of stiffening agent in combination with a lipase inhibitor and an open-celled polymeric foam. Because there is no teaching or suggestion at all, in any of the cited documents, to use a polymeric foam, there can be no expectation of success for using such a foam.

Finally, the cited documents do not disclose all of the claim limitations. For example, none of de Smidt, Maeder, or Hug teaches or suggests anything with respect to an open-celled polymeric foam.

Even assuming *arguendo* that one could combine the teachings of the cited documents, at best, one might arrive at a composition having a lipase inhibitor, a fatty acid/fatty acid salt, and a non-digestable food grade thickener, but one would not arrive at the presently claimed invention. Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

Conclusion

In light of the remarks and amendments presented herein, Applicants respectfully submit Claims 1, 3-36 and 71 are allowable over the cited reference. Reconsideration and allowance are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicant's undersigned attorney for further discussion.

Respectfully Submitted,

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